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SCHEMES, SCAMS AND FLIM-FLAMS: HOW THE DME SUPPLIER CAN RECOGNIZE FRAUD LANDMINES

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INTRODUCTION

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- When Medicare first came into existence, there were about 23 million of the "Greatest Generation" who were starting to retire.
- As time progressed, the Greatest Generation became older and required additional health care.

INTRODUCTION

- Health care services evolved as it provided health care to the aging World War II generation.
- This evolution spawned the DME industry. The DME industry, as we know it today, has been around since the early to mid 70s.
- Until the advent of the 21st century, there was little government oversight of the DME industry.

INTRODUCTION

- This lack of government oversight makes sense. The 28-year old legislative aids on Capitol Hill, and their bosses (Representatives and Senators) had no idea what a "DME supplier" was.
- The reason is simple. Young, healthy people go to hospitals, physicians, and suppliers. However, as a general rule, DME suppliers are for the elderly. Unless a staffer/elected official had taken care of an elderly relative, there was no reason for the staffer/elected official to step foot onto the premises of a DME supplier.
- For the same reasons, officials with HCFA (now CMS) really did not have any familiarity with DME suppliers.

INTRODUCTION

- This lack of familiarity with the DME industry started changing in the 1990s.
- The 23 million of the Greatest Generation started being supplanted by the 78 million Baby Boomers (those born between 1946 and 1964). Boomers are retiring at the rate of 10,000 per day.
- Elected officials and regulators started taking notice of the transition from the Greatest Generation to Boomers and the resulting financial burden this would place on the Medicare program.

INTRODUCTION

- The words "entitlement reform" entered the nation's vocabulary. Simply stated, "entitlement reform" means those steps that the country must take to keep Medicare and Social Security solvent.
- At the same time, the elected officials and regulators started taking notice of the DME industry.
- This "notice" resulted from two principle factors.
  - CMS noticed increasing outlays of money for DME under Part B.
  - A number of fraudulent schemes, pertaining to DME suppliers, made the headlines.

INTRODUCTION

- As a result, the industry is witnessing an increasing number of civil and criminal investigations brought against DME suppliers by the Department of Justice ("DOJ"), Office of Inspector General ("OIG"), state Attorney General Offices, and other federal and state government agencies.
- This program will discuss key federal anti-fraud laws and will then discuss what triggers government investigations.

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ANTI-FRAUD LEGAL GUIDELINES

MEDICARE ANTI-KICKBACK STATUTE

- The Medicare Anti-Kickback Statute ("AKS") makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person or entity to refer an individual for the furnishing or arranging for the furnishing of any item or service reimbursable by a federal health care program (e.g., Medicare, Medicare Advantage, Medicaid, TRICARE), or to induce such person to purchase or lease or recommend the purchase or lease of any item or service reimbursable by a federal health care program.

BENEFICIARY INDUCEMENT STATUTE

- Imposes civil monetary penalties upon a person or entity that offers or gives remuneration to any Medicare/ Medicaid beneficiary that the offeror knows or should know is likely to influence the recipient to order an item for which payment may be made under a federal or state health care program.

BENEFICIARY INDUCEMENT STATUTE

- This statute does not prohibit the giving of incentives that are of "nominal value" (no more than $10 per item or $50 in the aggregate to any one beneficiary on an annual basis).

ANTI-SOLICITATION STATUTE

- A DME supplier of a covered item may not contact a Medicare beneficiary by telephone regarding the furnishing of a covered item unless:
  - (i) the beneficiary has given written permission for the contact;
  - (ii) a supplier has previously provided the covered item to the beneficiary and the supplier is contacting the beneficiary regarding the covered item; or

ANTI-SOLICITATION STATUTE

- (iii) if the telephone contact is regarding the furnishing of a covered item other than an item already furnished to the beneficiary, the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.

STARK PHYSICIAN SELF-REFERRAL STATUTE

- Provides that if a physician has a financial relationship with an entity providing designated health services ("DHS"), then the physician may not refer patients to the entity unless one of the statutory or regulatory exceptions apply.
- DHS includes prescription drugs and DME.

SAFE HARBORS

- Because of the breadth and scope of the AKS, the OIG has published a number of "safe harbors." If an arrangement meets the requirements of a safe harbor, then as a matter of law the arrangement does not violate the AKS. If an arrangements does not meet the requirements of a safe harbor, then it does not mean that the arrangement automatically violates the AKS. Rather, the arrangement must be carefully scrutinized under the wording of the AKS, court decisions, and published guidance by the OIG.
- Set out hereafter are five of the most important safe harbors for suppliers.

SMALL INVESTMENT INTEREST

- For investments in small entities, “remuneration” does not include a return on the investment if a number of standards are met, including the following: (i) no more than 40% of the investment can be owned by persons who can generate business for or transact business with the entity, and (ii) no more than 40% of the gross revenue may come from business generated by investors.

SPACE RENTAL

- Remuneration does not include a lessee's payment to a lessor as long as a number of standards are met, including the following:
  - (i) the lease agreement must be in writing and signed by the parties;
  - (ii) the lease must specify the premises covered by the lease
  - (iii) if the lease gives the lessee periodic access to the premises, then it must specify exactly the schedule, the intervals, the precise length, and the exact rent for each interval;

SPACE RENTAL

- (iv) the term must be for not less than one year; and
- (v) the aggregate rental charge must be set in advance, be consistent with fair market value, and must not take into account business generated between the lessor and the lessee.

EQUIPMENT RENTAL

- Remuneration does not include any payment by a lessee of equipment to the lessor of equipment as long as a number of standards are met, including the following:
  - (i) the lease agreement must be in writing and signed by the parties;
  - (ii) the lease must specify the equipment;
  - (iii) for equipment to be leased over periods of time, the lease must specify exactly the scheduled intervals, their precise length and exact rent for each interval;

EQUIPMENT RENTAL

- (iv) the term of the lease must be for not less than one year; and
- (v) the rent must be set in advance, be consistent with fair market value, and must not take into account any business generated between the lessor and the lessee.

PERSONAL SERVICES & MANAGEMENT CONTRACTS

- Remuneration does not include any payment made to an independent contractor as long as a number of standards are met, including the following:
  - (i) the agreement must be in writing and signed by the parties;
  - (ii) the agreement must specify the services to be provided;
  - (iii) if the agreement provides for services on a sporadic or part-time basis, then it must specify exactly the scheduled intervals, their precise length and the exact charge for each interval;

PERSONAL SERVICES & MANAGEMENT CONTRACTS

- (iv) the term of the agreement must be for not less than one year;
- (v) the compensation must be set in advance, be consistent with fair market value, and must not take into account any business generated between the parties; and
- (vi) the services performed must not involve a business arrangement that violates any state or federal law.

EMPLOYEES

- Remuneration does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made, in whole or in part, under Medicare or under a state health care program.

ADVISORY OPINIONS

- A health care provider may submit to the OIG a request for an advisory opinion concerning a business arrangement that the provider has entered into or wishes to enter into in the future.
- In submitting the advisory opinion request, the provider must give to the OIG specific facts.
- In response, the OIG will issue an advisory opinion concerning whether or not there is a likelihood that the arrangement will implicate the AKS.

SPECIAL FRAUD ALERTS & SPECIAL ADVISORY BULLETINS

- From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive, and educate health care providers concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry.

STATES

- Most states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some statutes only apply when the payor is a government health care program.
- Other statutes that apply regardless of the identity of the payor.

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W-2 EMPLOYEE VS. 1099 INDEPENDENT CONTRACTOR

W-2 VS. 1099

- The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents.
- In Advisory Opinion No. 06-02, the OIG stated that "[p]ercentage compensation arrangements are inherently problematic under the Anti-Kickback Statute, because they relate to the volume or value of business generated between the parties."

W-2 VS. 1099

- A number of courts have held that marketing arrangements are illegal under the AKS and are, therefore, unenforceable.
- For example, the 1996 Florida *Medical Development Network* case involved an agreement wherein a durable medical equipment supplier agreed to pay an independent contractor marketing company (the "Marketer") a percentage of the DME supplier's sales in exchange for marketing its products to physicians, nursing homes, and others.

W-2 VS. 1099

- When the DME supplier breached the contract, the Marketer sued, and the DME supplier defended on the ground that the agreement was illegal under the AKS.
- A Florida appeals court agreed and affirmed the trial court's ruling, holding that the agreement was illegal and unenforceable because the Marketer's receipt of a percentage of the sales it generates for the DME supplier violated the federal AKS.

W-2 VS. 1099

- In recent years, there have been a number of enforcement actions involving commission payments to independent contractors.
- In one example, a home health agency agreed to pay $130,000 after disclosing that it paid commissions for each patient referred to the home health agency by 1099 independent contractor sales representatives.

W-2 VS. 1099

- Additionally, the OIG has taken the position that even when an arrangement will only focus on commercial patients and "carve out" beneficiaries of federally-funded health care programs, the arrangement will still likely violate the AKS.

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GIFTS TO PHYSICIANS

INTRODUCTION

- A physician is a referral source to the DME supplier.
- The physician refers patients who are covered by a government health care program, who are covered by commercial insurance, or desire to pay cash.
- If a supplier pays money to a physician for services, or provides meals, gifts and entertainment to a physician, or subsidizes a trip that the physician will take, then both the supplier and the physician need to comply with the federal and state laws that govern these arrangements.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- While Stark allows a supplier to spend up to $392 per year for non-cash/non-cash equivalent items for a physician, the AKS does not include a similar exception.
- Nevertheless, if the Stark exception is met, it is unlikely that the government will take the position that the non-cash/non-cash equivalent items provided by the supplier to the physician violate the AKS.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- In addition to complying with Stark and the AKS, the supplier and the physician also need to comply with applicable state law.
- Even though the supplier and the physician will need to confirm this, it is likely that compliance with the $392 Stark exception will avoid liability under state law.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- And so the bottom line is that a supplier can provide gifts, entertainment, trips, meals, and similar items to a physician so long as the combined value of all of these items do not exceed $392 in a 12-month period.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- For example, if a supplier wants a physician to accompany the supplier on a trip to a continuing education conference, then the supplier can safely subsidize up to $392 of the physician's trip expenses.
- The amount of the trip subsidy will be affected by other expenditures the supplier has made on behalf of the physician within the preceding 12 months.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- Separate from furnishing gifts and entertainment, and subsidizing trips, the supplier can pay the physician for legitimate services.
- For example, if the supplier has a legitimate need for a Medical Director, then the supplier and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the AKS and the Personal Services exception to Stark.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- Another legitimate way for money to exchange hands between a supplier and a physician is for the physician to rent space to the supplier or vice versa.
- The rental arrangement needs to comply with the Space Rental safe harbor to the AKS.
- This safe harbor is similar to the PSMC safe harbor.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- Among other requirements:
  - the parties must execute a written lease agreement that has a term of at least one year;
  - the rent paid must be fixed one year in advance (e.g., $48,000 over the next 12 months), and
  - the rent must be fair market value.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- The rental arrangement needs to also comply with the Space Rental exception to Stark; this exception is similar to the Space Rental safe harbor to the AKS.

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EMPLOYEE LIAISON

EMPLOYEE LIAISON

- A DME supplier may designate an employee to be on a facility's premises for a certain number of hours each week.
- The employee may educate the facility staff regarding medical equipment (to be used in the home) and related services.
- The employee liaison may not assume responsibilities that the facility is required to fulfill.
- Doing so will save the facility money, which will likely constitute a violation of the AKS.

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MEDICAL DIRECTOR AGREEMENT

MEDICAL DIRECTOR AGREEMENT

- A DME supplier can enter into an independent contractor Medical Director Agreement with a physician.
- The MDA must comply with the (i) Personal Services and Management Contracts safe harbor and (ii) the Personal Services exception to the Stark physician self-referral statute.

MEDICAL DIRECTOR AGREEMENT

- Requirements of the safe harbor and Stark exception include the following
  - Written agreement with a term of at least one year
  - They physician must give valuable services…not “made up services”
  - The compensation paid by the DME supplier must be fixed one year in advance (e.g., $6000 over the next 12 months, or $500 per month)
  - The compensation must be the fair market value equivalent of the physician’s services

MEDICAL DIRECTOR AGREEMENT

- "Sham" medical director arrangements are under the OIG's spotlight
- On June 9, 2015, the OIG addressed this issue by issuing a Fraud Alert entitled "Physician Compensation Arrangements May Result in Significant Liability." The Fraud Alert states:

MEDICAL DIRECTOR AGREEMENT

- Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide. Although many compensation arrangements are legitimate, a compensation arrangement may violate the AKS if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business. OIG encourages physicians to carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them.

MEDICAL DIRECTOR AGREEMENT

- OIG recently reached settlements with 12 individual physicians who entered into questionable medical directorship and office staff arrangements. OIG alleged that the compensation paid to these physicians under the medical directorship arrangements constituted improper remuneration under the AKS for a number of reasons, including that the payments took into account the physicians' volume or value of referrals and did not reflect fair market value for the services to be performed, and because the physicians did not actually provide the services called for under the agreements.

MEDICAL DIRECTOR AGREEMENT

- OIG also alleged that some of the 12 physicians had entered into arrangements under which an affiliated health care entity paid the salaries of the physicians' front office staff. Because these arrangements relieved the physicians of a financial burden they otherwise would have incurred, OIG alleged that the salaries paid under these arrangements constituted improper remuneration to the physicians. OIG determined that the physicians were an integral part of the scheme and subject to liability under the Civil Monetary Penalties Law.

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PURCHASE OF INTERNET LEADS

PURCHASE OF INTERNET LEADS

- When a supplier signs a lead generation agreement ("LGA") with a lead generation company ("LGC"), there are two main legal issues that must be addressed.
- The first one involves the AKS.
- In the eyes of the OIG, there is a distinction between (i) a "raw" or "unqualified" lead and (ii) a "qualified" lead.
- While it is normally acceptable to purchase "raw" or "unqualified" leads on a per lead basis, the AKS will likely be violated if "qualified" leads are purchased on a per lead basis.

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"SHAM" TELEHEALTH ARRANGEMENTS

SHAM TELEHEALTH ARRANGEMENTS

- Suppliers are aggressively engaged in marketing and it is not uncommon for a supplier to dispense drugs to patients residing in multiple states.
- When a supplier is marketing to patients in multiple states, the supplier may run into a "bottleneck."
- This involves the patient's local physician. A patient may desire to purchase a prescription drug from the out-of-state supplier but it is too inconvenient for the patient to drive to his physician's office.

SHAM TELEHEALTH ARRANGEMENTS

- Or if the patient is seen by his local physician, the physician may decide that the patient does not need the drug and so the physician refuses to sign a prescription.
- Or even if the physician does sign a prescription, he may be hesitant to send the order to an out-of-state supplier.

SHAM TELEHEALTH ARRANGEMENTS

- A typical telehealth company has contracts with many physicians who practice in multiple states.
- The telehealth company contracts with, and is paid by (i) self-funded employers that pay a membership fee for their employees, (ii) health plans, and (iii) patients who pay a per visit fee.
- Where a supplier will find itself in trouble is when it aligns itself with a telehealth company that is not paid by employers, health plans and patients – but rather – is directly or indirectly paid by the supplier.

SHAM TELEHEALTH ARRANGEMENTS

- Here is an example: *supplier purchases leads from a marketing company…the marketing company sends the leads to the telehealth company…the telehealth company contacts the leads and schedules audio or audio/visual encounters with physicians contracted with the telehealth company…the physicians sign prescriptions for drugs…the telehealth company sends the prescriptions to the supplier…the marketing company pays compensation to the telehealth company for its services in contacting the leads and setting up the physician appointments…the telehealth company pays the physicians for their patient encounters…the supplier mails the drug to the patient…the supplier bills (and gets paid by) Medicare.*

SHAM TELEHEALTH ARRANGEMENTS

- There can be a number of permutations to this example, but you get the picture.
- **Stripping everything away, the supplier is paying the ordering physician.**

SHAM TELEHEALTH ARRANGEMENTS

- To the extent that a supplier directly or indirectly pays money to a telehealth company, which in turn writes a prescription for drugs that will be dispensed by the supplier, the arrangement will likely be viewed as remuneration for a referral (or remuneration for "arranging for" a referral).

SHAM TELEHEALTH ARRANGEMENTS

- If the payer is a federal health care program, then the arrangement will likely violate the AKS.
- If the payer is the state Medicaid program, then the arrangement will likely violate both the AKS and the state anti-kickback statute.
- If the payer is a commercial insurer, then the arrangement may violate a state statute.

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UTILIZATION OF A MARKETING COMPANY

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- In the real world, it is common for a business to "outsource" marketing to a marketing company.
- Unfortunately, what works in the real world often does not work in the supplier universe. An example of this has to do with marketing companies.
- If a marketing company generates patients for a supplier, when at least some of the patients are covered by a government health care program, then the supplier cannot pay commissions to the marketing company.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- The AKS makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person to refer an individual for the furnishing or arranging for the furnishing of any Medicare-covered item or service, or to induce such person to purchase or lease or recommend the purchase or lease of any Medicare-covered item or service.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- The OIG has adopted safe harbors that provide immunity for arrangements that satisfy certain requirements.
- The employee safe harbor permits an employer to pay an employee in whatever manner the employer chooses in exchange for the employee assisting in the solicitation of federal health care program business, as long as there is a bona fide employer-employee relationship.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- The only way that an independent contractor can be paid for marketing or promoting Medicare-covered items or services is if the arrangement complies with the personal services and management contracts safe harbor.
- This safe harbor permits payments to referral sources as long as a number of requirements are met.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- Two of the requirements are that (i) payments must be pursuant to a written agreement with a term of at least one year, and (ii) the aggregate compensation paid to the independent contractor must be set in advance (e.g., $24,000 over the next 12 months), be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents.
- In Advisory Opinion No. 06-02, the OIG stated that "[p]ercentage compensation arrangements are inherently problematic under the Anti-Kickback Statute, because they relate to the volume or value of business generated between the parties." Moreover, in Advisory Opinion No. 99-3, the OIG stated:

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, "Sellers").
- Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the AKS, irrespective of the methodology used to compensate the agent.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee.
- For these reasons, this Office has a longstanding concern with independent sales agency arrangements.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- Further, in its response to comments submitted when the safe harbor regulations were originally proposed, the OIG stated:
  - [M]any commentators suggested that we broaden the [employee safe harbor] to apply to independent contractors paid on a commission basis.
  - We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- Additionally, the OIG has taken the position that even when an arrangement will only focus on commercial patients and "carve out" beneficiaries of federally-funded health care programs, the arrangement will still likely violate the AKS.

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LOAN/CONSIGNMENT CLOSETS

LOAN/CONSIGNMENT CLOSETS

- A DME supplier may place inventory in a hospital or physician office. The inventory must be for the convenience only of the hospital's/physician's patients and the hospital/physician cannot financially benefit, directly or indirectly, from the inventory.
- If a DME supplier pays rent for a space in which the consigned inventory is placed, then the arrangement should comply with the Space Rental safe harbor.

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QUESTIONS?

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THANK YOU

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